SH

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OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 16-R-0029

Customer Number: 55

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

Boehringer Ingelheim Pharmaceuticals Inc
900 Ridgebury Road, Po Box 368
Ridgefield, CT 06877

Telephone: (203) 798 9988

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)*

FACILITY LOCATIONS *(Sites)* *See Attached Listing*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	12	54	202	20	276
5. Cats	0	0	0	0	0
6. Guinea Pigs	19	4	105	200	309
7. Hamsters	0	0	0	0	0
8. Rabbits	0	10	0	0	10
9. Non-human Primates	0	31	80	34	145
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O. | NAME AND TITLE OF C.E.O. OR I.O. (Type or Print) | DATE SIGNED

(b)(6), (b)(7)c

Nov 12, 2009

APHIS FORM 7023
AUG 2009

EC 12-3-09

NOV 16 2009

E4.

Twenty dogs assigned to Column E of this report were used in non-clinical laboratory studies to evaluate the safety of test compounds in accordance to Food and Drug Administration requirements under Good Laboratory Practice regulations 21 CFR 58. These animals were orally dosed with test articles and experienced clinical signs of diarrhea, emesis and dilated pupils. All clinical signs resolved within 24 hours of dosing. The dogs were not given other drugs such as analgesics or sedatives that might cause reversal of histological toxic effects of the test article or induce their own inherent toxicities or drug-drug interactions.

E6

200 guinea pigs assigned to Column E of this report were used in non-clinical laboratory studies to screen product lots for potential to elicit delayed hypersensitivity reaction to specific trace component. The animals were sensitized to the specific component through administration of that agent in conjunction with complete and incomplete Freund's adjuvant, followed by a subsequent challenge dose of the product ten days later. The delayed hypersensitivity reaction was expressed as a degree of foot swelling in the guinea pigs. The volume of swelling was measured at the ten day time point. No analgesics were administered during the ten day time period because those agents had the potential to minimize the swelling which was the end point that was to be measured and therefore could interfere with the accurate interpretation of the properties of the product lots being screened.

Facility Registration Number 16- R -0029

E9

Three monkeys assigned to Column E of this report were used in non-clinical laboratory studies to evaluate the safety of test articles in accordance to the Food and Drug Administration requirements under Good Laboratory Practice regulations, 21 CFR 58. The animals were used on studies to determine potential target organs of toxicity and no effect levels of test articles that were administered by oral gavage. Following multiple dosing, the animals developed clinical signs of nose bleed, decreased motor activity and skin rash. The animals were not given other drugs such as tranquilizers or analgesics that might cause reversal of the histological toxic effects of the test article or induce their own inherent toxicities or drug-drug interactions.

Thirty-one macaque monkeys assigned to Column E of this report were used in non-clinical laboratory studies to evaluate the safety of test articles in accordance to the Food and Drug Administration requirements under Good Laboratory Practice regulations, 21 CFR 58. The animals were used on studies to determine potential target organs of toxicity and no effect levels of test articles that were administered by oral gavage. Following multiple dosing, the animals developed clinical signs of diarrhea, emesis and weight loss. The animals were not given other drugs such as tranquilizers or analgesics that might cause reversal of the histological toxic effects of the test article or induce their own inherent toxicities or drug-drug interactions.